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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Note to applicant: The marked up version of the claims submitted in response to the last office action appears to have a typographical error in withdrawn claim 7. In line 2 of this claim the number "1" is both deleted (lined through) and added (underlined) to the claim when it appears that it should have only been added (underlined).

Election/Restrictions

To summarize the current election, applicant elected invention group III.

New claims 30-34 would be categorized in invention group I. Thus claims 30-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morcol et al. (previously cited) in view of Keller (previously cited) and Baker et al. (previously cited).

Morcol et al. teach a composition to deliver insulin to the bloodstream via oral administration and to protect the compound form degradation or denaturation while in transit to the blood stream (see page 3 line 21-page 4 line 17 and page 11 lines 14-21). Specifically, Morcol et al. teach a particulate composition where calcium phosphate,

insulin, and polyethylene glycol (hydrophilic matrix) are combined as the core that is surrounded by the lipophilic casein (see page 24-26; instant claim 1). Morcol et al. go on to teach that these particles are sized in the range of 1-10 μm and can be encapsulated in any conventional oral delivery system (see page 21 lines 26-30; instant claim 1). Specifically, Morcol et al. teach the incorporation of multiple taught particles into gelatin capsules (gastric protection) (see page 12 line 30-page 13 line 2; instant claim 18) Morcol et al. do not teach the particles being in an additional lipophilic compound within the capsule.

Keller teaches a drug containing particulate lipophilic vector that is included with a liquid carrier (propylene glycol) in a gelatin capsule, where the capsule is coated with an enteric polymeric coating (see column 4 lines 22-29 and example 1; instant claims 1 and 18). Further Keller teaches that the gelatin capsules are negatively affected by the presence of water in the material they contain (see column 4 lines 5-6). Keller does not teach that this liquid carrier is lipophilic.

Baker et al. teach a drug containing lipophilic particulate composition that is taught to be delivered with a pharmaceutically acceptable carrier (see column 25 lines 14-27 and column 26 lines 3-4). Baker et al. go on to teach a set of glycols and oils that are particularly envisioned as such a carrier, where a variety of animal oils, mineral oils, and organic oils are named (see column 26 lines 6-10; instant claims 1 and 17).

Applicant teaches that soaking or spraying of the matrix with the lipophilic chemical species is sufficient to achieve the claimed "weak bonds" with the matrix surface (see instant specification paragraph 40). Morcol et al. teach the “soaking” of

their particles in the lipophilic casein, thereby forming a layer of casein around and "weakly" bonded to each particle (see page 11 lines 24- 31 and page 26 lines 5-11). The teachings of Keller et al. provide a gelatin capsule that holds a liquid carrier (polyethylene glycol) and active containing particulates. Baker teaches equivalent liquid carriers for pharmaceutical particulates that include both glycols and oils. It would have been obvious to one of ordinary skill in the art at the time of the invention to combine these teachings and use one of the oils taught by Baker et al. instead of the glycol used as the liquid carrier in the gelatin capsule of Keller et al. Further it also would have been obvious to employ this gelatin capsule configuration in the invention of Morcol et al. as it was an option well within the technical grasp of one of ordinary skill in the art at the time of the invention for the gelatin capsule encapsulation of particulate pharmacological actives, as taught by Morcol et al. Therefore claims 1 and 17-18 are obvious over Morcol et al. in view of Keller and Baker et al.

Response to Arguments

Applicant's arguments filed October 23, 2008 have been fully considered but they are not persuasive. Applicant argues that Morcol et al. do not teach 1) a hydrophilic core, 2) a weakly bonded lipophilic coating on the matrix, 3) the delivery of the active to the blood stream, or 4) an additional lipophilic compound.

1) Morcol does teach a hydrophilic core in their teachings of the hydrophilic polyethylene glycol as a key component of the particle cores (see pages 24-26).

2) Applicant teaches that soaking or spraying of the matrix with the lipophilic chemical species is sufficient to achieve the claimed "weak bonds" with the matrix surface (see instant specification paragraph 40). Morcol et al. teach the "soaking" of their particles in the lipophilic casein, thereby forming a layer of casein around and "weakly" bonded to each particle (see page 11 lines 24- 31 and page 11 page 26 lines 5-11). If such an application process produces "weak bonds" when employed by applicant then the same results when utilized by Morcol et al.

3) Morcol et al. does teach that their composition is designed to deliver the contained active to the bloodstream. In fact such delivery is the purpose of the Morcol et al. invention. Specifically they teach the oral delivery of insulin via their invention such that the insulin would be delivered to the bloodstream and that this administration route would be a viable alternative to subcutaneous injection of insulin (see page 4 lines 3-25). Their particular preparation is taught to be robust enough to protect the contained active while it travels through the acidic stomach environment and be released for ultimate delivery to the bloodstream within the small intestine.

4) The office action already indicated that Morcol et al. did not explicitly teach the presence of an additional lipophilic compound.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., weak bonds of chemical species to matrix that are removed by contact with microvilli and do not allow leakage of active substance form matrix) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification,

limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CARALYNNE HELM whose telephone number is

(571)270-3506. The examiner can normally be reached on Monday through Thursday 8-5 (EDT).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Caralynne Helm/
Examiner, Art Unit 1615

/MP WOODWARD/
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